IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN SALES, LLC, Plaintiff, v. SANDOZ INC., Defendant.	Civil Action No. 2:15-cv-00347 Judge Rodney Gilstrap
SANDOZ INC., Counterclaim Plaintiff, v. ALLERGAN SALES, LLC AND ALLERGAN, INC., Counterclaim Defendants.	

ANSWER TO PLAINTIFF
ALLERGAN SALES, LLC'S COMPLAINT BY SANDOZ INC.

Defendant Sandoz Inc. ("Sandoz") hereby responds to the Complaint of plaintiff Allergan Sales, LLC ("Allergan"), as follows:

The Nature of the Action

1. This is an action for infringement of United States Patent Nos. 7,030,149 ("the '149 patent"), 7,320,976 ("the '976 patent"), the 7,642,258 ("the '258 patent"), and the 8,748,425 ("the '425 patent") under 35 U.S.C. § 271(e)(2) and for Declaratory Judgment of infringement under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a), (b), and (c) relating to Allergan's commercially successful product, Combigan®.

ANSWER: Sandoz admits that Allergan purports to bring this action for infringement of the '149, '976, '258, and '425 patents under 35 U.S.C. § 271(e)(2) and for Declaratory Judgment of infringement under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a), (b), and (c). Sandoz denies all remaining allegations of paragraph 1.

The Parties

2. Allergan is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 2525 Dupont Drive, Irvine, California 92612.

ANSWER: Upon information and belief, Sandoz admits the allegations in paragraph 2.

3. On information and belief, Sandoz is a Colorado corporation with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

ANSWER: Sandoz admits that Sandoz is a Colorado corporation. Sandoz's principal place of business is at 100 College Road West, Princeton, New Jersey 08540. Sandoz denies all remaining allegations of paragraph 3.

4. On information and belief, Sandoz is in the business of manufacturing, distributing and selling generic drugs throughout the United States, including in this judicial district.

ANSWER: Sandoz admits that it develops, manufactures, and sells quality pharmaceutical products. Sandoz denies all remaining allegations of paragraph 4.

Jurisdiction and Venue

5. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq*. and the Declaratory Judgment Act. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

ANSWER: Paragraph 5 contains legal allegations and conclusion to which no answer is required. To the extent any answer is necessary, Sandoz admits that Allergan's complaint purports to arise under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.* and the Declaratory Judgment Act, and that this Court may exercise subject matter jurisdiction over such a complaint under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

6. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Paragraph 6 contains legal allegations and conclusions to which no answer is required. To the extent any is necessary, Sandoz does not admit that venue in this judicial district is proper. However, Sandoz waives its objection to venue for the purposes of this action only. Sandoz denies the remaining allegations of paragraph 6.

7. Allergan operates a facility in Waco, Texas where it manufactures and distributes numerous pharmaceutical products, including Combigan® (brimonidine tartrate/timolol maleate ophthalmic solution 0.2%/0.5%). Allergan's Combigan® product sold in the United States is exclusively manufactured in Allergan's Waco facility from which Allergan also coordinates the nationwide distribution of Combigan®. Allergan employs over 600 individuals in Texas, more than in any other U.S. state, except California. Were Sandoz to sell or offer to sell its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% product, Allergan will be injured specifically in Texas.

ANSWER: Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 7 and on that basis denies these allegations.

8. This Court has specific personal jurisdiction over Sandoz because the conduct complained of herein is directed at Allergan, a resident of the state of Texas, and Sandoz's conduct threatens and causes injury to Allergan through Allergan's Texas facilities and employees. In this regard, Sandoz, either directly or through an agent, regularly does or solicits business in this jurisdiction, engages in other persistent courses of conduct in this jurisdiction, and/or derives substantial revenue from services or things used or consumed in this jurisdiction.

ANSWER: Paragraph 8 contains legal allegations and conclusions to which no answer is required. To the extent any is necessary, Sandoz does not admit that personal jurisdiction in this judicial district is proper. However, Sandoz waives its objection to personal jurisdiction for the purposes of this action only. Sandoz denies the remaining allegations of paragraph 8.

9. On information and belief, Sandoz is a licensed drug distributor in Texas and has established contacts with Texas wholesalers, retailers, and state agencies to further the sales of its products.

ANSWER: Sandoz objects to and therefore denies the allegations in paragraph 9 because they go beyond a short and plain statement and/or contain mixed allegations of law and fact. To the extent the allegations of paragraph 9 go to allegations of personal jurisdiction, Sandoz does not admit that personal jurisdiction in this judicial district is proper. However, Sandoz waives its objection to personal jurisdiction for the purposes of this action only.

10. On information and belief, Sandoz's drug products are listed on the Texas prescription drug formulary.

ANSWER: Sandoz objects to and therefore denies the allegations in paragraph 10 because they go beyond a short and plain statement and/or contain mixed allegations of law and fact. To the extent the allegations of paragraph 10 go to allegations of personal jurisdiction,

Sandoz does not admit that personal jurisdiction in this judicial district is proper. However, Sandoz waives its objection to personal jurisdiction for the purposes of this action only.

11. On information and belief, Sandoz markets and sells generic drugs manufactured by Sandoz throughout Texas, including in this judicial district. On information and belief, Sandoz sold approximately $600 million of its products in Texas in 2014 to wholesalers, which accounted for over $1.5 billion in retail sales. On information and belief, approximately $78 million of those sales to wholesalers were in this judicial district. Sandoz continues to achieve substantial sales in both Texas and this judicial district.

ANSWER: Sandoz objects to and therefore denies the allegations in paragraph 11 because they go beyond a short and plain statement and/or contain mixed allegations of law and fact. To the extent the allegations of paragraph 11 go to allegations of personal jurisdiction, Sandoz does not admit that personal jurisdiction in this judicial district is proper. However, Sandoz waives its objection to personal jurisdiction for the purposes of this action only.

12. Sandoz knows and intends that its proposed Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will be distributed and sold in Texas and will displace sales of Allergan's Combigan® product causing injury to Allergan in Texas. Sandoz also intends to take advantage of its established channels of distribution in Texas for the sale of its proposed Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%. These channels of distribution were arranged by Sandoz to take advantage of the Texas market, the second-largest market for prescription drugs in the United States.

ANSWER: Sandoz admits that it intends to make and sell its proposed generic product, but Sandoz objects to all remaining allegations in paragraph 12 because they are indefinite and on that basis denies them.

13. On information and belief, Sandoz previously availed itself of this forum for purposes of litigating patent disputes regarding its ANDA products, including regarding its ANDA No. 91-087 for generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%, the product at issue here. In particular, Sandoz submitted to the jurisdiction of this Court and filed counterclaims in prior disputes over the product at issue in this litigation, Allergan, Inc. v. Sandoz Inc. et al., 2:09-cv-00097-TJW, D.I. 83 at 17-25 (E.D. Tex.); Allergan, Inc. v. Sandoz Inc. et al., 2:12-cv-00207-JRG, D.I. 92 at 51-62 (E.D. Tex.). Moreover, C.A. No. 2:09-cv-0097-TJW involved three of the four patents at issue in this litigation, the ’149, ’976, and ’258 patents.

ANSWER: Sandoz admits that it previously filed compulsory counterclaims in this forum, but Sandoz denies all remaining allegations of paragraph 13.

14. This Court has previously found a generic pharmaceutical manufacturer was subject to specific personal jurisdiction in an action with facts similar to those present here. Allergan, Inc. v. Actavis, Inc., C.A. No. 2:14-cv-638, 2014 WL 7336692 (E.D. Tex. Dec. 23, 2014).

ANSWER: Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 14 and on that basis denies these allegations.

15. This Court further has personal jurisdiction over Sandoz by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein.

ANSWER: Paragraph 15 contains legal allegations and conclusions to which no answer is required. To the extent any is necessary, Sandoz does not admit that personal jurisdiction in this judicial district is proper. However, Sandoz waives its objection to personal

jurisdiction for the purposes of this action only. Sandoz denies the remaining allegations of paragraph 15.

Background

16. The '149 patent, entitled "Combination of Brimonidine Timolol For Topical Ophthalmic Use," issued to Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L. Batoosingh on April 18, 2006. A copy of the '149 patent is attached to this complaint as Exhibit A.

ANSWER: Sandoz admits that the '149 patent is entitled "Combination of Brimonidine Timolol for Topical Ophthalmic Use," and that the patent states on its face that it was issued, naming Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L. Batoosingh as inventors, on April 18, 2006. Sandoz admits that Exhibit A appears to be a copy of the '149 patent. Sandoz denies all remaining allegations of paragraph 16.

17. Allergan, as assignee, owns the entire right, title, and interest in the '149 patent.

ANSWER: Sandoz admits that Allergan purports to have an ownership right, title, and interest in the '149 patent and that the '149 patent states on its face that Allergan, Inc. is the assignee of the patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining factual allegations in paragraph 17 and on that basis denies these allegations.

18. The '976 patent, entitled "Combination of Brimonidine And Timolol For Topical Ophthalmic Use," issued, naming Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L. Batoosingh as inventors, on January 22, 2008. A copy of the '976 patent is attached to this complaint as Exhibit B.

ANSWER: Sandoz admits that the ’976 patent is entitled “Combination of Brimonidine And Timolol for Topical Ophthalmic Use,” and that the patent states on its face that it was issued to Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L. Batoosingh on January 22, 2008. Sandoz admits that Exhibit B appears to be a copy of the ’976 patent. Sandoz denies all remaining allegations of paragraph 18.

19. Allergan, as assignee, owns the entire right, title, and interest in the ’976 patent.

ANSWER: Sandoz admits that Allergan purports to have an ownership right, title, and interest in the ’976 patent and that the ’976 patent states on its face that Allergan, Inc. is the assignee of the patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining factual allegations in paragraph 19 and on that basis denies these allegations.

20. The ’258 patent, entitled “Combination of Brimonidine And Timolol For Topical Ophthalmic Use,” issued to Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L. Batoosingh on January 5, 2010. A copy of the ’258 patent is attached to this complaint as Exhibit C.

ANSWER: Sandoz admits that the ’258 patent is entitled “Combination of Brimonidine And Timolol for Topical Ophthalmic Use,” and that the patent states on its face that it was issued, naming Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L. Batoosingh as inventors, on January 5, 2010. Sandoz admits that Exhibit C appears to be a copy of the ’258 patent. Sandoz denies all remaining allegations of paragraph 20.

21. Allergan, as assignee, owns the entire right, title, and interest in the ’258 patent.

ANSWER: Sandoz admits that Allergan purports to have an ownership right, title, and interest in the ’258 patent and that the ’258 patent states on its face that Allergan, Inc. is the

assignee of the patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining factual allegations in paragraph 21 and on that basis denies these allegations.

22. The ’425 patent, entitled “Combination of Brimonidine And Timolol For Topical Ophthalmic Use,” issued to Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L. Batoosingh on June 10, 2014. A copy of the ’425 patent is attached to this complaint as Exhibit D.

ANSWER: Sandoz admits that the ’425 patent is entitled “Combination of Brimonidine And Timolol for Topical Ophthalmic Use,” and that the patent states on its face that it was issued, naming Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L. Batoosingh as inventors, on June 10, 2014. Sandoz admits that Exhibit D appears to be a copy of the ’425 patent. Sandoz denies all remaining allegations of paragraph 22.

23. Allergan, as assignee, owns the entire right, title, and interest in the ’425 patent.

ANSWER: Sandoz admits that Allergan purports to have an ownership right, title, and interest in the ’425 patent and that the ’425 patent states on its face that Allergan is the assignee of the patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining factual allegations in paragraph 23 and on that basis denies these allegations.

24. Allergan is the holder of an approved New Drug Application (“NDA”) No. 21-398 for brimonidine tartrate/timolol maleate ophthalmic solution 0.2%/0.5%, sold under the Combigan® trademark.

ANSWER: Sandoz admits that New Drug Application No. 21-398 for brimonidine tartrate/timolol maleate ophthalmic solution 0.2%/0.5%, sold under the Combigan® trademark, states on its face that Allergan, Inc. is the holder of NDA No. 21-398. Sandoz lacks knowledge

or information sufficient to form a belief about the truth of the remaining factual allegations in paragraph 24 and on that basis denies these allegations.

25. In conjunction with that NDA, Allergan has listed with the United States Food and Drug Administration ("FDA") six patents that cover the approved formulation or methods of using the approved formulation of Combigan®. The listed patents are the '149 patent, the '976 patent, the '258 patent, the '425 patent, and U.S. Patent Nos. 8,133,890 and 8,354,409 (collectively, "the Listed Patents"). The FDA has published these six patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."

ANSWER: Sandoz admits that the electronic version of the FDA publication, Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book"), lists U.S. Patent Nos. 7,323,463; 8,133,890; and 8,354,409; the '149 patent; the '976 patent; the '258 patent; and the '425 patent for the product, Combigan. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining factual allegations in paragraph 25 and on that basis denies these allegations.

26. Combigan® or approved methods of using Combigan® are covered by at least one claim of each of the Listed Patents, including the '149, '976, '258, and '425 patents.

ANSWER: Paragraph 26 states legal conclusions to which no response is required. To the extent that a response is required, Sandoz denies the remaining allegations of paragraph 26.

27. On November 20, 2008, Sandoz submitted its ANDA No. 91-087 to the FDA, seeking approval to commercially manufacture, use, offer for sale, or sell a generic version of

Combigan®. Sandoz's ANDA No. 91-087 received tentative approval from the FDA on May 11, 2011.

ANSWER: Sandoz admits the allegations in paragraph 27.

28. In an August 22, 2011 opinion, the District Court for the Eastern District of Texas found that Sandoz's proposed generic version of Combigan® infringed U.S. Patent Nos. 7,030,149, 7,320,976, 7,323,463, and 7,642,258, and that those patents were not invalid. The Court entered an injunction order on August 25, 2011 stating that Sandoz is enjoined from manufacturing its proposed generic version of Combigan® until the latest of the expiration dates of U.S. Patent Nos. 7,030,149, 7,320,976, 7,323,463, and 7,642,258.

ANSWER: Sandoz admits that on August 22, 2011 the District Court for the Eastern District of Texas found that, among other proposed products, the drug product described in ANDA No. 91-087 infringed U.S. Patent Nos. 7,030,149, 7,320,976, 7,323,463, and 7,642,258. Sandoz further admits that, on that basis, the Court entered an injunction order on August 25, 2011. Sandoz denies the remaining allegations of paragraph 28.

29. On appeal, in a May 1, 2013 opinion, the Federal Circuit held that claim 4 of the '149 patent is not invalid, declined to rule on the validity of the '976 and '258 patents, and ruled that the claims of the '463 patent are invalid. In addition, the opinion affirmed the factual findings of this Court's August 22, 2011 opinion. Thereafter, Sandoz filed a petition for rehearing and rehearing *en banc*, which was denied on September 9, 2013, and a petition for a writ of certiorari to the Supreme Court which was denied on March 31, 2014.

ANSWER: Sandoz admits that the Federal Circuit issued an opinion on May 1, 2013, wherein the Federal Circuit held that the claims of the '463 patent are invalid and declined to rule on the validity of the '976 and '258 patents. Sandoz further admits that the Federal Circuit

denied the petition for rehearing on September 9, 2013, and that the Supreme Court denied certiorari on March 31, 2014. Sandoz denies the remaining allegations of paragraph 29.

30. In its petitions for rehearing and rehearing *en banc*, and in its petition for writ of certiorari, Sandoz asserted that it had amended its ANDA in an effort to avoid infringement of the '149 patent (the "Amendment"). Despite these new assertions, Sandoz did not provide a revised notice of Paragraph IV certification to Allergan at any time during the pendency of those petitions.

ANSWER: Sandoz objects to Allergan's definition of the term "Amendment" in paragraph 30 and all subsequent paragraphs as being argumentative and indefinite and on that basis denies the allegations of paragraph 30.

31. After the Federal Circuit denied Sandoz's rehearing petitions, Sandoz filed a motion for relief from this Court's judgment under Federal Rule of Civil Procedure 60 on September 17, 2013. That filing again referenced the Amendment. This Court denied that motion on December 3, 2013, and the Federal Circuit affirmed the judgment of this Court on December 11, 2014. Sandoz filed a petition for rehearing and rehearing *en banc* on February 11, 2015 at the Federal Circuit, which has not yet been decided.

ANSWER: Sandoz admits that Sandoz filed a motion on September 17, 2013, in this Court, that this Court denied that motion on December 3, 2013, and that a petition for rehearing with the Federal Circuit is pending. Sandoz denies the remaining allegations of paragraph 31.

32. At no time during the proceedings over its Rule 60 motion did Sandoz provide a revised notice of Paragraph IV certification to Allergan notifying Allergan of Sandoz's Amendment to its ANDA and its arguments regarding non-infringement of the '149 patent.[1]

[1] On April 13, 2012, Allergan filed suit against Sandoz in this Court in C.A. No. 2:12-cv-207, asserting infringement initially of U.S. Patent No. 8,133,890 and later also of U.S. Patent No.

ANSWER: After the District Court's August 22, 2011 decision, Sandoz amended its patent certification at least twice. On March 13, 2013, Sandoz amended its patent certification to include a Paragraph IV certification to U.S. Patent No. 8,133,890 ("the '890 patent"). On June 19, 2013, Sandoz submitted to the FDA an amended patent certification, which included both a new Paragraph IV certification to U.S. Patent No. 8,354,409 ("the '409 patent"), and a statement under 21 U.S.C. § 355(j)(2)(A)(viii) ("section viii statement") regarding the '149 patent. The same day, Sandoz sent Allergan a Notice and Detailed Statement required by 21 U.S.C. § 355(j)(2)(B)(i)-(iv). On July 2, 2013, Sandoz also produced to Allergan the June 19, 2013 patent certification that was sent to the FDA. That certification included the section viii statement regarding the '149 patent. Thus, Allergan was notified of Sandoz's section viii statement and its relevance to the patent dispute regarding the '149 patent before the proceedings over its Rule 60 motion. Sandoz denies the remaining allegations in paragraph 32 but admits the allegations in footnote 1 to paragraph 32.

33. On or about January 26, 2015, Allergan received a letter dated January 23, 2015, signed on behalf of Sandoz by Jean Domenico.

ANSWER: Sandoz admits that Sandoz sent a letter dated January 23, 2015, signed on behalf of Sandoz by Jean Domenico. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 33 and on that basis denies these remaining allegations.

34. The January 23, 2015 letter states in part that "Sandoz has now amended its ANDA to include an additional certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV) to U.S. Patent No. 8,748,425." The letter alleges that "the claims of the '425 patent are invalid,

8,354,409. On December 18, 2013, the Court ordered that the case be stayed. The Court continued that stay in an order dated January 22, 2015.

unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Sandoz Product."

ANSWER: Sandoz admits the allegations in paragraph 34.

35. The letter also formally notified Allergan for the first time of Sandoz's Amendment referenced in paragraph 30 above. Based on the Amendment, in the January 23, 2015 letter, Sandoz also avers that claim 4 of the '149 patent is not infringed by the Sandoz Product reflected in the amended ANDA. The January 23, 2015 letter also states that Sandoz maintains and repeats its prior assertions that the '976 and '258 patents are invalid.

ANSWER: Sandoz admits that Sandoz avers in the January 23, 2015 letter that claim 4 of the '149 patent is not infringed by the Sandoz Product reflected in the amended ANDA. Sandoz further admits that the January 23, 2015 letter also states that Sandoz maintains and repeats its prior assertions that the '976 and '258 patents are invalid. Sandoz denies the remaining allegations of paragraph 35.

36. Included in the January 23, 2015 letter is a "Detailed Statement" of the factual and legal basis for Sandoz's opinion that the claims of the '149 patent, '258 patent, '976 patent, and '425 patent are invalid and/or will not be infringed by the manufacture, use or sale of the Sandoz Product. The letter includes a statement that if Allergan does not sue Sandoz for infringement of the '149, '976, '258, and '425 patents, Sandoz would file a declaratory judgment action on those patents.

ANSWER: Sandoz admits the allegations in paragraph 36.

37. Sandoz's letter does not reference prior findings and conclusions by this Court that were resolved against it that were affirmed by the Federal Circuit. Under the doctrines of collateral estoppel, law of the case, and other legal finality doctrines, Sandoz is precluded from

re-litigating issues that were finally decided against it in other litigations involving the subject matter that is at issue here.

ANSWER: Sandoz denies the allegations in paragraph 37.

38. Because Sandoz has submitted a new paragraph IV certification, however, and has amended its ANDA, Allergan files this suit to preserve its rights under the Hatch-Waxman Act, including its rights to a 30-month stay on approval of Sandoz's now amended ANDA. By filing this suit, Allergan does not intend to waive any rights that Sandoz may be precluded from re-litigating issues relevant to the infringement and/or validity of the previously adjudicated '149, '976, and '258 patents.

ANSWER: Sandoz denies the allegations in paragraph 38, and specifically denies any suggestion that Allergan is entitled to a 30 month stay.

39. In filing its ANDA, and submitting the Amendment, Sandoz has requested the FDA's approval to market a generic version of Allergan's Combigan® product throughout the United States, including in Texas.

ANSWER: Sandoz admits that it submitted ANDA No. 91-087 to the FDA, seeking approval to commercially manufacture, use, offer for sale, or sell the drug product described in the ANDA in the United States. Sandoz denies the remaining allegations of paragraph 39.

40. On information and belief, following FDA approval of ANDA Nos. 91-087, Sandoz will sell the approved generic version of Allergan's Combigan® product throughout the United States, including in Texas.

ANSWER: Sandoz admits that it submitted ANDA No. 91-087 to the FDA, seeking approval to commercially manufacture, use, offer for sale, or sell the drug product described in the ANDA in the United States. Sandoz denies the remaining allegations of paragraph 40.

Count I

(Infringement of Claim 4 of the ’149 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%)

41. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Sandoz incorporates by reference its answers to the allegations in paragraphs 1-40 as if fully set forth herein.

42. Sandoz submitted ANDA No. 91-087 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of its proposed Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% throughout the United States. By submitting that application and notifying Allergan, Sandoz has committed an act of infringement of claim 4 of the ’149 patent under 35 U.S.C. § 271(e)(2)(A). Further, by submitting its Amendment and notifying Allergan, Sandoz has committed an act of infringement of claim 4 of the ’149 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Sandoz admits that it submitted ANDA No. 91-087 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of the drug product described in the ANDA in the United States. Sandoz denies the remaining allegations of paragraph 42.

43. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will constitute an act of infringement of claim 4 of the ’149 patent.

ANSWER: Sandoz denies the allegations in paragraph 43.

44. On information and belief, Sandoz became aware of the ’149 patent no later than the date on which that patent was listed in the Orange Book.

ANSWER: Sandoz admits that it was aware of the ’149 patent at least as early as the date it sent its first notice letter regarding the ’149 patent. Sandoz denies the remaining allegations of paragraph 44.

45. On information and belief, Sandoz knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce and contribute to the actual infringement of claim 4 of the ’149 patent.

ANSWER: Sandoz denies the allegations in paragraph 45.

46. On information and belief, Sandoz knows or should know that its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will be especially made for or especially adapted for use in an infringement of claim 4 of the ’149 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively contribute to the actual infringement of claim 4 of the ’149 patent.

ANSWER: Sandoz denies the allegations in paragraph 46.

47. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% in violation of Allergan’s patent rights will cause harm to Allergan for which damages are inadequate.

ANSWER: Sandoz denies the allegations in paragraph 47.

Count II

(Declaratory Judgment of Infringement of Claim 4 of the '149 Patent under 35 U.S.C. § 271(b) and (c) by Sandoz's Proposed Generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%)

48. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Sandoz incorporates by reference its answers to the allegations in paragraphs 1-47 as if fully set forth herein.

49. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent that a response is required, Sandoz admits that plaintiff purports to state a claim under the Declaratory Judgment Act. Sandoz denies the remaining allegations of paragraph 49.

50. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent that a response is required, Sandoz admits that there is a justiciable controversy between Allergan and Sandoz regarding non-infringement of the '149 patent. Sandoz denies the remaining allegations of paragraph 50.

51. Sandoz has actual knowledge of the '149 patent.

ANSWER: Sandoz admits the allegations in paragraph 51.

52. On information and belief, Sandoz became aware of the '149 patent no later than the date on which that patent was listed in the Orange Book.

ANSWER: Sandoz admits that it was aware of the '149 patent at least as early as the date it sent its first notice letter regarding the '149 patent. Sandoz denies the remaining allegations of paragraph 52.

53. On information and belief, Sandoz has acted with full knowledge of claim 4 of the ’149 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of claim 4 of the ’149 patent.

ANSWER: Sandoz denies the allegations in paragraph 53.

54. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will induce the actual infringement of claim 4 of the ’149 patent.

ANSWER: Sandoz denies the allegations in paragraph 54.

55. On information and belief, Sandoz knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce the actual infringement of claim 4 of the ’149 patent.

ANSWER: Sandoz denies the allegations in paragraph 55.

56. On information and belief, Sandoz will encourage another’s infringement of the ’149 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%, which is covered by claim 4 of the ’149 patent.

ANSWER: Sandoz denies the allegations in paragraph 56.

57. Sandoz’s acts of infringement will be done with knowledge of claim 4 of the ’149 patent and with the intent to encourage infringement.

ANSWER: Sandoz denies the allegations in paragraph 57.

58. The foregoing actions by Sandoz will constitute active inducement of infringement of claim 4 of the ’149 patent.

ANSWER: Sandoz denies the allegations in paragraph 58.

59. On information and belief, Sandoz knows or should know that its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will be especially made or especially adapted for use in an infringement of claim 4 of the ’149 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Sandoz denies the allegations in paragraph 59.

60. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will contribute to the actual infringement of claim 4 of the ’149 patent.

ANSWER: Sandoz denies the allegations in paragraph 60.

61. On information and belief, Sandoz knows or should know that its offer for sale, sale and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will contribute to the actual infringement of claim 4 of the ’149 patent.

ANSWER: Sandoz denies the allegations in paragraph 61.

62. The foregoing actions by Sandoz will constitute contributory infringement of claim 4 of the ’149 patent.

ANSWER: Sandoz denies the allegations in paragraph 62.

63. On information and belief, Sandoz intends to, and will, actively induce and contribute to the infringement of claim 4 of the ’149 patent when ANDA No. 91-087 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

ANSWER: Sandoz denies the allegations in paragraph 63.

64. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% by Sandoz will induce and/or contribute to infringement of claim 4 of the '149 patent.

ANSWER: Sandoz denies the allegations in paragraph 64.

65. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%, which will actively induce and/or contribute to infringement of claim 4 of the '149 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

ANSWER: Sandoz denies the allegations in paragraph 65.

66. Unless Sandoz is enjoined from actively inducing and contributing to the infringement of claim 4 of the '149 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Sandoz denies the allegations in paragraph 66.

67. On information and belief, despite having actual notice of claim 4 of the '149 patent, Sandoz continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of claim 4 of the '149 patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

ANSWER: Sandoz denies the allegations in paragraph 67.

Count III

(Infringement of the ’976 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%)

68. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Sandoz incorporates by reference its answers to the allegations in paragraphs 1-67 as if fully set forth herein.

69. Sandoz submitted ANDA No. 91-087 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of its proposed Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% throughout the United States. By submitting that application and notifying Allergan, Sandoz has committed an act of infringement of the ’976 patent under 35 U.S.C. § 271(e)(2)(A). Further, by submitting its Amendment and notifying Allergan, Sandoz has committed an act of infringement of the ’976 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Sandoz admits that it submitted ANDA No. 91-087 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of the drug product described in the ANDA in the United States. Sandoz denies the remaining allegations of paragraph 69.

70. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will constitute an act of infringement of the ’976 patent.

ANSWER: Sandoz denies the allegations in paragraph 70.

71. On information and belief, Sandoz became aware of the ’976 patent no later than the date on which that patent was listed in the Orange Book.

ANSWER: Sandoz admits that it was aware of the ’976 patent at least as early as the date it sent its first notice letter regarding the ’976 patent. Sandoz denies the remaining allegations of paragraph 71.

72. On information and belief, Sandoz knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce and contribute to the actual infringement of the ’976 patent.

ANSWER: Sandoz denies the allegations in paragraph 72.

73. On information and belief, Sandoz knows or should know that its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will be especially made for or especially adapted for use in an infringement of the ’976 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively contribute to the actual infringement of the ’976 patent.

ANSWER: Sandoz denies the allegations in paragraph 73.

74. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% in violation of Allergan’s patent rights will cause harm to Allergan for which damages are inadequate.

ANSWER: Sandoz denies the allegations in paragraph 74.

Count IV

(Declaratory Judgment of Infringement of the ’976 Patent under 35 U.S.C. § 271(b) and (c) by Sandoz’s Proposed Generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%)

75. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Sandoz incorporates by reference its answers to the allegations in paragraphs 1-74 as if fully set forth herein.

76. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent that a response is required, Sandoz admits that plaintiff purports to state a claim under the Declaratory Judgment Act. Sandoz denies the remaining allegations of paragraph 76.

77. There is an actual case or controversy such that the Court may entertain Allergan’s request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent that a response is required, Sandoz admits that there is a justiciable controversy between Allergan and Sandoz regarding non-infringement of the ’976 patent. Sandoz denies the remaining allegations of paragraph 77.

78. Sandoz has actual knowledge of the ’976 patent.

ANSWER: Sandoz admits the allegations in paragraph 78.

79. On information and belief, Sandoz became aware of the ’976 patent no later than the date on which that patent was listed in the Orange Book.

ANSWER: Sandoz admits that it was aware of the ’976 patent at least as early as the date it sent its first notice letter regarding the ’976 patent. Sandoz denies the remaining allegations of paragraph 79.

80. On information and belief, Sandoz has acted with full knowledge of the ’976 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the ’976 patent.

ANSWER: Sandoz denies the allegations in paragraph 80.

81. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will induce the actual infringement of the ’976 patent.

ANSWER: Sandoz denies the allegations in paragraph 81.

82. On information and belief, Sandoz knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce the actual infringement of the ’976 patent.

ANSWER: Sandoz denies the allegations in paragraph 82.

83. On information and belief, Sandoz will encourage another’s infringement of the ’976 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%, which is covered by the ’976 patent.

ANSWER: Sandoz denies the allegations in paragraph 83.

84. Sandoz’s acts of infringement will be done with knowledge of the ’976 patent and with the intent to encourage infringement.

ANSWER: Sandoz denies the allegations in paragraph 84.

85. The foregoing actions by Sandoz will constitute active inducement of infringement of the ’976 patent.

ANSWER: Sandoz denies the allegations in paragraph 85.

86. On information and belief, Sandoz knows or should know that its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will be especially made or especially adapted for use in an infringement of the ’976 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Sandoz denies the allegations in paragraph 86.

87. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will contribute to the actual infringement of the ’976 patent.

ANSWER: Sandoz denies the allegations in paragraph 87.

88. On information and belief, Sandoz knows or should know that its offer for sale, sale and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will contribute to the actual infringement of the ’976 patent.

ANSWER: Sandoz denies the allegations in paragraph 88.

89. The foregoing actions by Sandoz will constitute contributory infringement of the ’976 patent.

ANSWER: Sandoz denies the allegations in paragraph 89.

90. On information and belief, Sandoz intends to, and will, actively induce and contribute to the infringement of the ’976 patent when ANDA No. 91-087 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

ANSWER: Sandoz denies the allegations in paragraph 90.

91. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s proposed generic

Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% by Sandoz will induce and/or contribute to infringement of the ’976 patent.

ANSWER: Sandoz denies the allegations in paragraph 91.

92. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%, which will actively induce and/or contribute to infringement of the ’976 patent, in violation of Allergan’s patent rights, will cause harm to Allergan for which damages are inadequate.

ANSWER: Sandoz denies the allegations in paragraph 92.

93. Unless Sandoz is enjoined from actively inducing and contributing to the infringement of the ’976 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Sandoz denies the allegations in paragraph 93.

94. On information and belief, despite having actual notice of the ’976 patent, Sandoz continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the ’976 patent in disregard of Allergan’s rights, making this case exceptional and entitling Allergan to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

ANSWER: Sandoz denies the allegations in paragraph 94.

Count V

(Infringement of the ’258 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%)

95. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Sandoz incorporates by reference its answers to the allegations in paragraphs 1-94 as if fully set forth herein.

96. Sandoz submitted ANDA No. 91-087 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of its proposed Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% throughout the United States. By submitting that application and notifying Allergan, Sandoz has committed an act of infringement of the '258 patent under 35 U.S.C. § 271(e)(2)(A). Further, by submitting its Amendment and notifying Allergan, Sandoz has committed an act of infringement of the '258 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Sandoz admits that it submitted ANDA No. 91-087 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of the drug product described in the ANDA in the United States. Sandoz denies the remaining allegations of paragraph 96.

97. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will constitute an act of infringement of the '258 patent.

ANSWER: Sandoz denies the allegations of paragraph 97.

98. On information and belief, Sandoz became aware of the '258 patent no later than the date on which that patent was listed in the Orange Book.

ANSWER: Sandoz admits that it was aware of the '258 patent at least as early as the date it sent its first notice letter regarding the '258 patent. Sandoz denies the remaining allegations of paragraph 98.

99. On information and belief, Sandoz knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Brimonidine

Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce the actual infringement of the ’258 patent.

ANSWER: Sandoz denies the allegations in paragraph 99.

100. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% in violation of Allergan’s patent rights will cause harm to Allergan for which damages are inadequate.

ANSWER: Sandoz denies the allegations in paragraph 100.

Count VI

(Declaratory Judgment of Infringement of the ’258 Patent Under 35 U.S.C. § 271(a) by Sandoz)

101. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Sandoz incorporates by reference its answers to the allegations in paragraphs 1-100 as if fully set forth herein.

102. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent that a response is required, Sandoz admits that plaintiff purports to state a claim under the Declaratory Judgment Act. Sandoz denies the remaining allegations of paragraph 49.

103. There is an actual case or controversy such that the Court may entertain Allergan’s request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent that a response is required, Sandoz admits that there is a justiciable controversy

between Allergan and Sandoz regarding non-infringement of the ’258 patent. Sandoz denies the remaining allegations of paragraph 103.

104. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will constitute an act of direct infringement of one or more claims of the ’258 patent.

ANSWER: Sandoz denies the allegations in paragraph 104.

105. On information and belief, Sandoz will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% immediately and imminently upon approval of ANDA No. 91-087.

ANSWER: Sandoz admits that it intends to market the drug products described in ANDA 91-087 in the United States after approval of Sandoz’s ANDA. Sandoz denies the remaining allegations of paragraph 105.

106. The foregoing actions by Sandoz will constitute infringement of the ’258 patent.

ANSWER: Sandoz denies the allegations in paragraph 106.

107. Sandoz will commit those acts of infringement without license or authorization.

ANSWER: Sandoz denies the allegations in paragraphs 107.

108. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% by Sandoz will infringe the ’258 patent.

ANSWER: Sandoz denies the allegations in paragraph 108.

109. Unless Sandoz is enjoined from infringing the ’258 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Sandoz denies the allegations in paragraph 109.

110. On information and belief, Sandoz became aware of the ’258 patent no later than the date on which that patent was listed in the Orange Book.

ANSWER: Sandoz admits that it was aware of the ’258 patent at least as early as the date it sent its first notice letter regarding the ’258 patent. Sandoz denies the remaining allegations of paragraph 110.

111. On information and belief, Sandoz has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%.

ANSWER: Sandoz denies the allegations in paragraph 111.

112. Sandoz’s actions indicate a refusal to change the course of its actions in the face of acts by Allergan.

ANSWER: Sandoz denies the allegations in paragraph 112.

113. On information and belief, Sandoz has acted, and will continue to act, with full knowledge of the ’258 patent and without a reasonable basis for believing that it would not be liable for infringing the ’258 patent.

ANSWER: Sandoz denies the allegations in paragraph 113.

114. On information and belief, despite having actual notice of the ’258 patent, Sandoz continues to willfully, wantonly, and deliberately prepare to infringe the ’258 patent in disregard

of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

ANSWER: Sandoz denies the allegations in paragraph 114.

Count VII

(Declaratory Judgment of Infringement of the '258 Patent under 35 U.S.C. § 271(b) and (c) by Sandoz's Proposed Generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%)

115. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Sandoz incorporates by reference its answers to the allegations in paragraphs 1-114 as if fully set forth herein.

116. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent that a response is required, Sandoz admits that plaintiff purports to state a claim under the Declaratory Judgment Act. Sandoz denies the remaining allegations of paragraph 116.

117. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent that a response is required, Sandoz admits that there is a justiciable controversy between Allergan and Sandoz regarding non-infringement of the '258 patent. Sandoz denies the remaining allegations of paragraph 117.

118. Sandoz has actual knowledge of the '258 patent.

ANSWER: Sandoz admits the allegations in paragraph 118.

119. On information and belief, Sandoz became aware of the ’258 patent no later than the date on which that patent was listed in the Orange Book.

ANSWER: Sandoz admits that it was aware of the ’258 patent at least as early as the date it sent its first notice letter regarding the ’258 patent. Sandoz denies the remaining allegations of paragraph 119.

120. On information and belief, Sandoz has acted with full knowledge of the ’258 patent and without a reasonable basis for believing that it would not be liable for actively inducing the infringement of the ’258 patent.

ANSWER: Sandoz denies the allegations of paragraph 120.

121. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will induce the actual infringement of the ’258 patent.

ANSWER: Sandoz denies the allegations of paragraph 121.

122. On information and belief, Sandoz knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce the actual infringement of the ’258 patent.

ANSWER: Sandoz denies the allegations of paragraph 122.

123. On information and belief, Sandoz will encourage another’s infringement of the ’258 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%, which is covered by certain claims of the ’258 patent.

ANSWER: Sandoz denies the allegations of paragraph 123.

124. Sandoz's acts of infringement will be done with knowledge of the '258 patent and with the intent to encourage infringement.

ANSWER: Sandoz denies the allegations of paragraph 124.

125. The foregoing actions by Sandoz will constitute active inducement of infringement of the '258 patent.

ANSWER: Sandoz denies the allegations of paragraph 125.

126. On information and belief, Sandoz knows or should know that its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will be especially made or especially adapted for use in an infringement of the '258 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Sandoz denies the allegations of paragraph 126.

127. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will contribute to the actual infringement of the '258 patent.

ANSWER: Sandoz denies the allegations of paragraph 127.

128. On information and belief, Sandoz knows or should know that its offer for sale, sale and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will contribute to the actual infringement of the ' 258 patent.

ANSWER: Sandoz denies the allegations of paragraph 128.

129. The foregoing actions by Sandoz will constitute contributory infringement of the '258 patent.

ANSWER: Sandoz denies the allegations of paragraph 129.

130. On information and belief, Sandoz intends to, and will, actively induce and contribute to the infringement of the ’258 patent when ANDA No. 91-087 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

ANSWER: Sandoz denies the allegations of paragraph 130.

131. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% by Sandoz will induce and/or contribute to infringement of the ’258 patent.

ANSWER: Sandoz denies the allegations of paragraph 131.

132. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%, which will actively induce and/or contribute to infringement of the ’258 patent, in violation of Allergan’s patent rights, will cause harm to Allergan for which damages are inadequate.

ANSWER: Sandoz denies the allegations of paragraph 132.

133. Unless Sandoz is enjoined from actively inducing and contributing to the infringement of the ’258 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Sandoz denies the allegations of paragraph 133.

134. On information and belief, despite having actual notice of the ’258 patent, Sandoz continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the ’258 patent in disregard of Allergan’s rights, making this case exceptional and entitling Allergan to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

ANSWER: Sandoz denies the allegations of paragraph 134.

Count VIII

(Infringement of the ’425 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%)

135. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Sandoz incorporates by reference its answers to the allegations in paragraphs 1-134 as if fully set forth herein.

136. Sandoz submitted ANDA No. 91-087 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of its proposed Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% throughout the United States. By submitting that application and notifying Allergan, Sandoz has committed an act of infringement of the ’425 patent under 35 U.S.C. § 271(e)(2)(A). Further, by submitting its Amendment and notifying Allergan, Sandoz has committed an act of infringement of the ’425 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Sandoz admits that it submitted ANDA No. 91-087 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of the drug product described in the ANDA in the United States. Sandoz denies the remaining allegations of paragraph 136.

137. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will constitute an act of infringement of the ’425 patent.

ANSWER: Sandoz denies the allegations of paragraph 137.

138. On information and belief, Sandoz became aware of the ’425 patent no later than the date on which that patent was listed in the Orange Book.

ANSWER: Sandoz admits that it was aware of the ’425 patent at least as early as the date it sent its first notice letter regarding the ’425 patent. Sandoz denies the remaining allegations of paragraph 138.

139. On information and belief, Sandoz knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce and contribute to the actual infringement of the ’425 patent.

ANSWER: Sandoz denies the allegations in paragraph 139.

140. On information and belief, Sandoz knows or should know that its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will be especially made for or especially adapted for use in an infringement of the ’425 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively contribute to the actual infringement of the ’425 patent.

ANSWER: Sandoz denies the allegations in paragraph 140.

141. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% in violation of Allergan’s patent rights will cause harm to Allergan for which damages are inadequate.

ANSWER: Sandoz denies the allegations in paragraph 141.

Count IX

(Declaratory Judgment of Infringement of the ’425 Patent under 35 U.S.C. § 271(b) and (c) by Sandoz’s Proposed Generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%)

142. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Sandoz incorporates by reference its answers to the allegations in paragraphs 1-141 as if fully set forth herein.

143. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent that a response is required, Sandoz admits that plaintiff purports to state a claim under the Declaratory Judgment Act. Sandoz denies the remaining allegations of paragraph 143.

144. There is an actual case or controversy such that the Court may entertain Allergan’s request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent that a response is required, Sandoz admits that there is a justiciable controversy between Allergan and Sandoz regarding non-infringement of the ’425 patent. Sandoz denies the remaining allegations of paragraph 144.

145. Sandoz has actual knowledge of the ’425 patent.

ANSWER: Sandoz admits the allegations in paragraph 145.

146. On information and belief, Sandoz became aware of the ’425 patent no later than the date on which that patent was listed in the Orange Book.

ANSWER: Sandoz admits that it became aware of the ’425 patent at least as early as the date it sent its first notice letter regarding the ’425 patent. Sandoz denies the remaining allegations of paragraph 146.

147. On information and belief, Sandoz has acted with full knowledge of the ’425 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the ’425 patent.

ANSWER: Sandoz denies the allegations in paragraph 147.

148. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will induce the actual infringement of the ’425 patent.

ANSWER: Sandoz denies the allegations in paragraph 148.

149. On information and belief, Sandoz knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce the actual infringement of the ’425 patent.

ANSWER: Sandoz denies the allegations in paragraph 149.

150. On information and belief, Sandoz will encourage another’s infringement of the ’425 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%, which is covered by certain claims of the ’425 patent.

ANSWER: Sandoz denies the allegations in paragraph 150.

151. Sandoz’s acts of infringement will be done with knowledge of the ’425 patent and with the intent to encourage infringement.

ANSWER: Sandoz denies the allegations in paragraph 151.

152. The foregoing actions by Sandoz will constitute active inducement of infringement of the ’425 patent.

ANSWER: Sandoz denies the allegations in paragraph 152.

153. On information and belief, Sandoz knows or should know that its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will be especially made or especially adapted for use in an infringement of the ’425 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Sandoz denies the allegations in paragraph 153.

154. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will contribute to the actual infringement of the ’425 patent.

ANSWER: Sandoz denies the allegations in paragraph 154.

155. On information and belief, Sandoz knows or should know that its offer for sale, sale and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will contribute to the actual infringement of the ’425 patent.

ANSWER: Sandoz denies the allegations in paragraph 155.

156. The foregoing actions by Sandoz will constitute contributory infringement of the ’425 patent.

ANSWER: Sandoz denies the allegations in paragraph 156.

157. On information and belief, Sandoz intends to, and will, actively induce and contribute to the infringement of the ’425 patent when ANDA No. 91-087 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

ANSWER: Sandoz denies the allegations in paragraph 157.

158. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s proposed generic

Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% by Sandoz will induce and/or contribute to infringement of the ’425 patent.

ANSWER: Sandoz denies the allegations in paragraph 158.

159. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz’s proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%, which will actively induce and/or contribute to infringement of the ’425 patent, in violation of Allergan’s patent rights, will cause harm to Allergan for which damages are inadequate.

ANSWER: Sandoz denies the allegations in paragraph 159.

160. Unless Sandoz is enjoined from actively inducing and contributing to the infringement of the ’425 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Sandoz denies the allegations in paragraph 160.

161. On information and belief, despite having actual notice of the ’425 patent, Sandoz continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the ’425 patent in disregard of Allergan’s rights, making this case exceptional and entitling Allergan to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

ANSWER: Sandoz denies the allegations in paragraph 161.

JURY TRIAL DEMAND

Sandoz objects to Allergan’s jury demand as improper.

PRAYER FOR RELIEF

Sandoz denies all allegations not expressly admitted herein. Sandoz denies that Allergan is entitled to any of the relief requested in the prayer for relief, or any relief whatsoever.

AFFIRMATIVE DEFENSES

Sandoz asserts the following affirmative defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Sandoz reserves the right to amend its Answer and conform its pleadings to the evidence as additional information becomes available.

First Affirmative Defense

(Non-infringement of the ’149 Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of the product that is the subject of Sandoz’s ANDA No. 91-087 does not and would not directly, indirectly, contributorily and/or by inducement, infringe any properly issued, valid, and enforceable claim of the ’149 patent, either literally or under the doctrine of equivalents.

Second Affirmative Defense

(Non-infringement of the ’976 Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of the product that is the subject of Sandoz’s ANDA No. 91-087 does not and would not directly, indirectly, contributorily and/or by inducement, infringe any properly issued, valid, and enforceable claim of the ’976 patent, either literally or under the doctrine of equivalents.

Third Affirmative Defense

(Invalidity of the ’976 Patent)

Upon information and belief, the ’976 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more

provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

Fourth Affirmative Defense

(Non-infringement of the ’258 Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of the product that is the subject of Sandoz’s ANDA No. 91-087 does not and would not directly, indirectly, contributorily and/or by inducement, infringe any properly issued, valid, and enforceable claim of the ’258 patent, either literally or under the doctrine of equivalents.

Fifth Affirmative Defense

(Invalidity of the ’258 Patent)

Upon information and belief, the ’258 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

Sixth Affirmative Defense

(Non-infringement of the ’425 Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of the product that is the subject of Sandoz’s ANDA No. 91-087 does not and would not directly, indirectly, contributorily and/or by inducement, infringe any properly issued, valid, and enforceable claim of the ’425 patent, either literally or under the doctrine of equivalents.

Seventh Affirmative Defense

(Invalidity of the '425 Patent)

Upon information and belief, the '425 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

Eighth Affirmative Defense

(Statutory Bar to Cost Recovery)

Allergan and Allergan, Inc. are barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

Ninth Affirmative Defense

(Miscellaneous Reservation of Rights)

Sandoz asserts the above defenses without the benefit of full discovery and investigation, and reserves the right to supplement or amend these affirmative defenses as necessary, including its right to add an affirmative defense of invalidity regarding claim 4 of the '149 patent should that claim be held to be invalid in another proceeding.

SANDOZ'S COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Sandoz, by way of its attorneys The Davis Firm PC and Morrison & Foerster LLP, hereby states the following for its Counterclaims against Allergan and Allergan, Inc.

1. Sandoz repeats and incorporates by reference each of the foregoing paragraphs of Sandoz's Answer to Plaintiff and Counterclaim Defendant Allergan Sales, LLC's Complaint.

The Nature of the Action

2. Plaintiff Allergan, Inc. markets Combigan®, an ophthalmic combination of 0.2% brimonidine tartrate and 0.5% timolol maleate for the treatment of glaucoma or ocular hypertension. This cases stems from Sandoz Inc.'s submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") for approval to market a generic version of Combigan for the treatment of ocular hypertension. Sandoz already obtained a judgment of invalidity of U.S. Patent No. 7,323,463 ("the '463 patent") on May 1, 2013. Through these counterclaims, Sandoz seeks a declaratory judgment of non-infringement and/or invalidity regarding four patents related to the invalid '463 patent. Specifically, these counterclaims include requests for a declaratory judgment of non-infringement of U.S. Patent Nos. 7,030,149 ("the '149 patent") and 8,748,425 ("the '425 patent") and a declaratory judgment of invalidity of U.S. Patent Nos. 7,642,258 ("the '258 patent"), 7,320,976 ("the '976 patent"), and the '425 patent.

The Parties

3. Counterclaim Plaintiff Sandoz Inc. is a Colorado corporation with its principal place of business at 100 College Road West, Princeton, New Jersey 08540.

4. On information and belief, Counterclaim Defendant Allergan, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2525 Dupont Drive, Irvine, California 92612.

5. On information and belief, Counterclaim Defendant Allergan is a limited liability company organized and existing under the laws of the State of California, with a principal place of business at 2525 Dupont Drive, Irvine, California 92612.

Jurisdiction and Venue

6. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.* and the Declaratory Judgment Act. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

7. This Court has personal jurisdiction over defendants Allergan and Allergan, Inc. because they, either directly or through an agent, regularly do or solicit business in this jurisdiction, engage in other persistent courses of conduct in this jurisdiction, and derive substantial revenue from services or things used or consumed in this jurisdiction. Allergan, Inc. regularly does business in Texas, including this district. Allergan manufactures ophthalmic products in Waco, Texas.

8. Allergan, Inc. previously sued Sandoz in this District for allegedly infringing the ’149 patent, the ’976 patent, and the ’258 patent, all of which stem from the same patent application that led to the ’425 patent. In a separate lawsuit, Allergan, Inc. sued Sandoz for allegedly infringing two other patents, which share the same parent patent application as the ’425 patent. *See Allergan, Inc. v. Sandoz Inc.*, Case No. 09-cv-0097-JRG (E.D. Tex. filed Apr. 7, 2009); *Allergan Sales, Inc. v. Sandoz Inc.*, Case No. 2:12-CV-00207-JRG, (E.D. Tex. filed Apr. 13, 2012). After Allergan, Inc. sued Sandoz in the second lawsuit, Allergan substituted for Allergan, Inc. as the sole plaintiff. *Allergan Sales, LLC v. Sandoz Inc.*, No. 2:12-cv-207-JRG, ECF No. 105 (E.D. Tex. Apr. 3, 2013).

9. Venue for Sandoz’s counterclaims is proper in this district pursuant to 28 U.S.C. § 1391.

Background

Factual and Regulatory Background

Hatch-Waxman Act Litigation

10. The Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act, provides a mechanism by which competing pharmaceutical companies can bring generic versions of branded drugs to market. An applicant that wishes to market a generic version of a drug may file an ANDA with the FDA. 21 U.S.C. § 355(j). The generic drug must be bioequivalent to an FDA-approved drug listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book." *Id.* § 355(j)(2)(A)(iv).

11. To file an ANDA for Orange Book patents that have not yet expired, the applicant may certify either that the patent is invalid, unenforceable, or that the ANDA product will not infringe (a "Paragraph IV certification"). *Id.* § 355(j)(2)(A)(vii)(IV). The first ANDA applicant for a given Orange Book drug to make a Paragraph IV certification receives a 180-day period of marketing exclusivity for its ANDA product upon the first marketing of the ANDA product. *Id.* § 355(j)(5)(B)(iv).

12. Upon the filing of a Paragraph IV certification in an ANDA, the patent holder may file suit for patent infringement within 45 days from receipt of notice of the certification. 21 U.S.C. § 355(j)(5)(B)(iii).

Section viii Design-Arounds

13. An ANDA applicant may design around a patent by submitting a "section viii statement" asserting that it will market its proposed ANDA product for only those methods of use not covered by the brand's patent. *See* 21 U.S.C. § 355(j)(2)(A)(viii). When submitting a section viii statement, the ANDA applicant also must propose a label that "carves out" the still-

patented methods of use. *See generally Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676-77 (2012). This procedure allows the FDA to approve an ANDA even though some patent protection still exists for the branded drug.

Orange Book Patents

14. Allergan, Inc. has listed in the Orange Book seven patents purported to be to formulations and methods of use for Combigan®, the branded drug purportedly consisting primarily of a combination of 0.2% brimonidine tartrate and 0.5% timolol maleate. Allergan, Inc. markets Combigan as a treatment for both glaucoma and ocular hypertension.

15. The seven Orange Book patents stem from the same parent patent application. The issued patents include the ’149 patent, the ’976 patent, the ’258 patent, and the ’425 patent, as well the now-invalid ’463 patent, U.S. Patent No. 8,133,890 (“the ’890 patent”), and 8,354,409 (“the ’409 patent”). On May 1, 2013, the United States Court of Appeals for the Federal Circuit held the ’463 patent to be invalid for obviousness. *See Allergan, Inc. v. Sandoz Inc.*, 726 F. 3d 1286, 1295 (Fed. Cir. 2013) (“Brim Tim I”). The ’890 and ’409 patents are currently being litigated before this Court in a second case (“Brim Tim II”). That case has been stayed pending the outcome of Sandoz’s appeal in Brim Tim I. *Allergan v. Sandoz Inc.*, No. 2:12-cv-207-JRG, ECF No. 213 (E.D. Tex. Jan. 22, 2015). The ’149 patent claims a method of treating glaucoma or ocular hypertension. During Brim Tim I, on August 25, 2011, this Court held that claims 1-3 of the ’149 patent were not infringed by Sandoz’s proposed product, and the Federal Circuit affirmed the claim construction supporting the judgment of noninfringement in its May 1, 2013 opinion. Claim 4 of the ’149 patent is the only claim among the 20 asserted claims in Brim Tim I that was expressly held not to be invalid by the Federal Circuit.

16. At the time that this Court tried Brim Tim I, Sandoz's ANDA sought approval for a generic version of Combigan that would be indicated for both ocular hypertension and glaucoma patients. When that version of Sandoz' ANDA was pending before the FDA, on August 2, 2011, Sandoz stipulated to infringement of claim 4 of the '149 patent in Brim Tim I.

17. On its face, the '149 patent is entitled "Combination of brimonidine timolol for topical ophthalmic use." It issued on April 18, 2006.

18. On its face, the '976 patent is entitled "Combination of brimonidine and timolol for topical ophthalmic use." It issued on January 22, 2008.

19. On its face, the '258 patent is entitled "Combination of brimonidine and timolol for topical ophthalmic use." It issued on January 5, 2010.

20. On its face, the '425 patent is entitled "Combination of brimonidine and timolol for topical ophthalmic use." It issued on June 10, 2014.

21. Allergan, Inc. caused the Patent and Trademark Office to record an Assignment of Assignors' Interest for the '149, '976, '258, and '425 patents to Allergan. Allergan, Inc. remains the holder of the New Drug Application for Combigan.

Procedural History

22. Sandoz submitted ANDA No. 91-087 on November 20, 2008, seeking FDA approval to market a generic version of Allergan, Inc.'s Combigan product. Sandoz was the first to file an ANDA with a Paragraph IV certification for the then-listed Orange Book patents for Combigan. Allergan, Inc. sued Sandoz in this Court on April 7, 2009, alleging patent infringement based on the ANDA existing at the time of the Complaint. Sandoz counterclaimed, arguing at trial, among other things, that Allergan, Inc.'s patents were invalid for obviousness under 35 U.S.C. § 103.

23. On August 2, 2011, the first day of trial in Brim Tim I, Sandoz narrowed the issues for trial by stipulating to infringement under 35 U.S.C. § 271(e)(2). After a bench trial on the issue of invalidity, this Court held that the asserted patent claims were not invalid and issued an injunction preventing Sandoz from marketing its ANDA product. *See Allergan, Inc. v. Sandoz Inc.*, 818 F. Supp. 2d 974, 1031-32 (E.D. Tex. 2011).

24. Sandoz appealed the non-invalidity judgments and the permanent injunction to the U.S. Court of Appeals for the Federal Circuit. On May 1, 2013, a Federal Circuit panel unanimously held the '463 patent to be invalid. *Allergan*, 726 F.3d at 1295. A divided panel upheld the validity of claim 4 of the '149 patent. *Id.* Relying on the validity of claim 4 of the '149 patent, the Federal Circuit deemed it "unnecessary" to address the '258 and '976 patents, failing to reach the merits of Sandoz's invalidity appeal. *Id.* at 1294 n.2 ("Because we conclude that claim 4 of the '149 patent is not invalid, [Sandoz] will be unable to enter the market until that date. Accordingly, we find it unnecessary to address the claims of the '258 and '976 patents.").

25. Sandoz then filed a petition for panel rehearing and rehearing *en banc*, which the Federal Circuit denied. *Allergan, Inc. v. Sandoz Inc.*, Nos. 2011-1619, -1620, -1635, & -1639, slip op. at 2 (Fed. Cir. Sept. 9, 2013). Sandoz filed a petition for a writ of certiorari, which the Supreme Court denied. *Sandoz Inc. v. Allergan, Inc.*, 134 S. Ct. 1764 (2014).

26. Following the Federal Circuit's decision, on June 19, 2013, Sandoz amended its ANDA by submitting to the FDA a section viii "design-around" statement and amended product label. The FDA later approved Sandoz's amended ANDA with the section viii statement. As amended, Sandoz's ANDA does not infringe claim 4 of the '149 patent, the only patent claim expressly found to be infringed and not invalid by the Federal Circuit in Brim Tim I. It claims

"[a] method of reducing the number of daily topical ophthalmic doses of brimonidine administered topically to an eye of a person in need thereof for the treatment of glaucoma or ocular hypertension from 3 to 2 times a day without loss of efficacy." '149 patent, col. 10, ll. 10-17. The claim specifies that "the concentration of brimonidine is 0.2% by weight." *Id.*, col. 10. ll. 14-15. Accordingly, to infringe claim 4 of the '149 patent, a patient must reduce his number of daily doses of 0.2% brimonidine from three times a day to two times a day. If an ocular hypertension patient is not taking 0.2% brimonidine three times per day before switching to a treatment in which 0.2% brimonidine is administered twice per day (*e.g.*, by taking Sandoz's proposed ANDA product twice per day) one cannot infringe the '149 patent.

27. Sandoz's original ANDA indicated that its product was indicated for use in patients with glaucoma or ocular hypertension. Sandoz's section viii design-around "carved out" the use of its ANDA product for glaucoma, while continuing to state that the product is indicated for use in patients with ocular hypertension. In the United States today, brimonidine is marketed in three concentrations: 0.1%, 0.15%, and 0.2%. Lower concentrations of brimonidine, i.e., brimonidine 0.1% and 0.15%, are the most prescribed brimonidine products with a combined market share of more than 75%. Doctors prefer to prescribe 0.15% or 0.1% brimonidine because the risk of side effects is lower. To the extent that some doctors still prescribe 0.2% brimonidine for patients with ocular hypertension, they prescribe it for twice-a-day or once-a-day application.

28. Ophthalmologists in the United States do not prescribe 0.2% brimonidine three times per day to patients with ocular hypertension. Patients with ocular hypertension do not take 0.2% brimonidine three times per day. Therefore, no ocular hypertension patients switch from a three-times-a day dosage of 0.2% brimonidine to a twice-a-day dosage of brimonidine/timolol

fixed combination. In other words, no ocular hypertension patients reduce the number of daily topical ophthalmic doses of brimonidine from three times a day to two times a day.

29. Sandoz has never directly infringed claim 4 of the ’149 patent. With treatment for glaucoma carved out, Sandoz is incapable of inducing others to directly infringe claim 4 of the ’149 patent.

30. After Sandoz designed around claim 4 of the ’149 patent to avoid future infringement allegations, Sandoz filed a motion with this Court to modify the injunction pursuant to Federal Rule of Civil Procedure 60(b)(5) and 60(b)(6). Sandoz requested that the injunction be modified so that it could launch its modified ANDA product, given that the section viii design-around rendered the ’149 patent not infringed. Sandoz further requested that this Court hold the ’258 and ’976 patents invalid in light of the reasoning leading to the Federal Circuit’s holding of invalidity of the ’463 patent. This Court denied the first request on the ground that Sandoz’s design-around was not an “unforeseen or unexpected” change in circumstances justifying relief under Rule 60(b)(5). *Allergan, Inc. v. Sandoz Inc.*, Nos. 2:09-CV-97, -348, -200, & -344, 2013 WL 6253669, at *3 (E.D. Tex. Dec. 3, 2013). This Court also ruled that it did not have jurisdiction to hear the merits of the invalidity arguments regarding the ’258 and ’976 patents because the Federal Circuit did not remand the case to this Court. *Id.* at *2. This Court also declined to address the merits of the validity the ’258 and ’976 patents. *Id.* at *2-3.

31. Sandoz appealed this Court’s denial of its Rule 60(b) motion to the Federal Circuit, which denied the petition without an opinion. *Allergan, Inc. v. Sandoz Inc.*, 587 F. App’x 657 (Fed. Cir. Dec. 11, 2014). Sandoz filed a petition for rehearing *en banc* on February 11, 2015. That petition remains pending.

32. On January 23, 2015, Sandoz sent a Notice Letter to Allergan and Allergan, Inc., noting that Sandoz continued to maintain ANDA No. 91-087 and continued to seek approval to engage in the commercial manufacture, use, and sale of generic version of Allergan, Inc.'s Combigan product before the expiration of the seven Orange Book-listed patents for Combigan. Sandoz intends to market its ANDA product in the United States as soon as legally permissible after approval of its ANDA in light of potential third party exclusivity rights.

Case or Controversy

33. Counts II, IV, VI, VII, and IX of Allergan's complaint are claims seeking declaratory judgment relief regarding the '149 patent, the '976 patent, the '258 patent, and the '425 patent. For each count, Allergan alleges that there is a sufficient case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III. For the same reasons, there is a sufficient case or controversy to establish this Court's authority to hear Sandoz's counterclaims.

34. By maintaining the Orange Book listing of the seven Orange Book patents in connection with the Combigan NDA, Allergan, Inc. continues to represent that the Orange Book-listed patents could reasonably be asserted against anyone making, using or selling a generic Combigan product without a license from Allergan, Inc.

35. Sandoz's current Paragraph IV certification states, among other things, that the '425 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, and/or offer for sale of Sandoz's ANDA product as described in ANDA No. 91-087. Sandoz's Notice Letter to Allergan also included a detailed statement of the factual and legal basis for Sandoz's opinion that the claims of the '149 patent, '258 patent, '976 patent, and '425 patent are

invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of Sandoz proposed ANDA product.

36. Since Sandoz submitted and the FDA accepted Sandoz's section viii design-around, no court has addressed the merits of Sandoz's non-infringement contentions regarding claim 4 of the '149 patent. Because the section viii design-around has changed the scope of the indicated use of Sandoz's ANDA product, this action is not based on the same set of transactional facts as the prior litigation regarding the '149 patent. Similarly, the issue of whether Sandoz's post-carve-out ANDA infringes claim 4 of the '149 patent is not identical to the issue in the prior litigation of whether Sandoz's earlier ANDA infringed the '149 patent. Allergan stated to the Federal Circuit that a new lawsuit was the appropriate forum for Sandoz to seek a declaration that its section viii design around does not infringe the '149 patent. *See, e.g.*, *Allergan, Inc. v. Sandoz Inc.*, Nos. 2014-1151, ECF No. 46 at 30 ("If Sandoz wishes to file a new paragraph IV certification or a new ANDA reflecting its [design-around], allowing Allergan to file another lawsuit for infringement on the supposed design-around as the Hatch-Waxman Act envisions, it is free to do so."); *see also id.* at 2.

37. Since this Court's findings of fact and conclusions of law in Brim Tim I, including the Federal Circuit's holding that the '463 patent is invalid for obviousness, no court has addressed the merits of Sandoz's invalidity contentions as to the '258 and '976 patents. Because the Federal Circuit declined to address the invalidity arguments as to those patents, Sandoz has not received a final judgment on the merits of the claims. Additionally, because the Court of Appeals has not rendered a decision on the validity of the '258 and '976 patents, and because the final invalidity of the '463 patent provides additional guidance regarding the invalidity of those patents, Sandoz has not had a full and fair opportunity to litigate the issue.

While the Federal Circuit entered judgment on Sandoz's appeal in Brim Tim I, it did so without considering the validity of the '258 and '976 patents. Accordingly, the validity of the '258 and '976 patents was not essential to the judgment the Federal Circuit entered.

38. No court has addressed Sandoz's claim of invalidity of the '425 patent, or whether Sandoz's ANDA infringes the '425 patent. Sandoz has also never previously brought a declaratory judgment claim for non-infringement, invalidity, or unenforceability as to the '425 patent. Sandoz continues to pursue the marketing of its ANDA product and seeks a declaration of the rights of the parties in relation to the unchallenged '425 patent.

Count I

(Declaratory Judgment of Non-Infringement of the '149 Patent)

39. Paragraphs 1-38 are incorporated herein as set forth above.

40. Sandoz has not infringed, induced infringement of, or contributed to the infringement of any valid claim of the '149 patent. The '149 patent claims a method of treating glaucoma or ocular hypertension. A method claim can only be infringed when every step of the method is performed. Sandoz's amended ANDA will not be used as a method of treatment that directly performs all of the steps of the method claims of the '149 patent. Thus, Sandoz cannot induce others to infringe the '149 patent.

41. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Due to Sandoz's continued intention to market a generic version of Combigan based on its section viii design-around, a case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by

this Court exists between Sandoz, on the one hand, and Allergan and Allergan, Inc., on the other hand, concerning the infringement of the claims of the ’149 patent.

42. Sandoz is entitled to a judicial determination that Sandoz has not and will not, induce infringement of, or contribute to infringement of, any valid claim of the ’149 patent under any infringement theory.

Count II

(Declaratory Judgment of Invalidity of the ’258 Patent)

43. Paragraphs 1-42 are incorporated herein as set forth above.

44. The claims of the ’258 patent are invalid for failing to comply with the requirements of the Patent Laws of the United States, particularly with regard to one or more of the requirements specified in Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code. For example, the claims are invalid for obviousness based on the same reasoning the Federal Circuit employed to invalidate the asserted claims of the ’463 patent in Brim Tim I.

45. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Because the Federal Circuit failed to render a decision on the validity of the ’258 patent, Sandoz has not had a full and fair opportunity to litigate the issue. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Sandoz, on the one hand, and Allergan and Allergan, Inc., on the other hand, concerning the invalidity of the ’258 patent.

46. Sandoz is entitled to a judicial determination that one or more claims of the ’258 patent are invalid for failing to comply with the requirements of the Patent Laws of the United States.

Count III

(Declaratory Judgment of Invalidity of the ’976 Patent)

47. Paragraphs 1-46 are incorporated herein as set forth above.

48. The sole claim of the ’976 patent is invalid for failing to comply with the requirements of the Patent Laws of the United States, particularly with regard to one or more of the requirements specified in Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code. For example, the claims are invalid for obviousness based on the same reasoning the Federal Circuit employed to invalidate the asserted claims of the ’463 patent in Brim Tim I.

49. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Because the Federal Circuit failed to render a decision on the validity of the ’976 patent, Sandoz has not had a full and fair opportunity to litigate the issue. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Sandoz, on the one hand, and Allergan and Allergan. Inc., on the other hand, concerning the invalidity of the ’976 patent.

50. Sandoz is entitled to a judicial determination that one or more claims of the ’976 patent are invalid for failing to comply with the requirements of the Patent Laws of the United States.

Count IV

(Declaratory Judgment of Invalidity of the ’425 Patent)

51. Paragraphs 1-50 are incorporated herein as set forth above.

52. One or more claims of the ’425 patent are invalid for failing to comply with the requirements of the Patent Laws of the United States, particularly with regard to one or more of

the requirements specified in Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

53. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Sandoz, on the one hand, and Allergan and Allergan, Inc., on the other hand, concerning the invalidity of the ’425 patent.

54. Sandoz is entitled to a judicial determination that one or more claims of the ’425 patent are invalid for failing to comply with the requirements of the Patent Laws of the United States.

Count V

(Declaratory Judgment of Non-Infringement of the ’425 Patent)

55. Paragraphs 1-54 are incorporated herein as set forth above.

56. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Sandoz, on the one hand, and Allergan and Allergan, Inc., on the other hand, concerning the infringement of the claims of the ’425 patent.

57. Sandoz is entitled to a judicial determination that Sandoz has not infringed, induced infringement of, or contributed to infringement of, any valid claim of the ’425 patent under any infringement theory.

Count VI

(Miscellaneous Reservation of Rights)

58. Sandoz asserts the above counterclaims without the benefit of full discovery and investigation, and reserves the right to supplement or amend these counterclaims as necessary, including its right to add a counterclaim of invalidity regarding claim 4 of the ’149 patent should that claim be held to be invalid in another proceeding.

PRAYER FOR RELIEF

WHEREFORE, Sandoz respectfully prays for relief as follows:

(i) Judgment declaring that no valid claim of the ’149 patent is infringed by Sandoz under any infringement theory;

(ii) Judgment declaring that the sole claim of the ’976 patent is invalid;

(iii) Judgment declaring that the claims of the ’258 patent are invalid;

(iv) Judgment declaring that one or more claims of the ’425 patent are invalid;

(v) Judgment declaring that no valid claim of the ’425 patent is infringed by Sandoz under any infringement theory;

(vi) Judgment enjoining Allergan, Allergan, Inc., and its agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof from threatening or initiating infringement litigation against Sandoz or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Sandoz, or charging them either orally or in writing with infringement of any patent asserted herein against Sandoz;

(vii) An award to Sandoz of its costs;

(viii) Judgment that this is an exceptional case and an award to Sandoz of its reasonable attorneys' fees under 35 U.S.C. § 285 and/or the inherent discretion of the Court; and

Such further relief as this Court may deem just, equitable and appropriate.

Dated: April 6, 2015

Respectfully Submitted,

By: /s/ William E. Davis, III

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a). As such, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email, on this the 6th day of April, 2015.

/s/ William E. Davis, III
William E. Davis, III